DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

State Health Fraud Task Force Grants; Availability of Funds; Request for Applications; Correction; Funding Opportunity Number: FDA–ORA–04–2; Catalog of Federal Domestic Assistance Number: 93.447

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

I. Funding Opportunity Description

The Food and Drug Administration (FDA) is announcing the availability of grant funds for State Health Fraud Task Force Grant Program support. This announcement supercedes previous announcements of this program, which were published in the **Federal Register** of June 28, 2004 (69 FR 36091), and February 28, 2005 (70 FR 9656). Grant funds will be used to assist agencies in identifying and prosecuting perpetrators of health fraud and acquired immunodeficiency syndrome (AIDS) health fraud; obtain and disseminate information on the use of fraudulent drugs and therapies; disseminate information on approved drugs and therapies; and provide health fraud information obtained by the State Health Fraud Task Force to State health agencies, community based organizations, and FDA staff.

FDA will support projects covered by this notice under sections 1702 through 1706 of title XVII of the Public Health Service Act (42 U.S.C. 300u-1 through 300u-5). FDA's project program is described in the Catalog of Federal Domestic Assistance, No. 93.447.

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The State Health Fraud Task Force has the following mission: (1) To assist and educate health professionals and persons with serious illnesses, and to educate them about the dangers and magnitude of health fraud; (2) to assist law enforcement agencies in identifying and prosecuting perpetrators of health fraud; (3) to obtain and disseminate information on the fraudulent drugs and therapies being used and the consequences of their use; (4) to disseminate information on approved drugs and therapies; and (5) to provide health fraud information obtained by the State Health Fraud Task Force to State health agencies, community based organizations, and FDA staff.

State Health Fraud Task Force grants will be awarded only for direct costs incurred to accomplish the mission of the State Health Fraud Task Force Program in educating and combating health fraud.

II. Award Information

Support of these grants will be for up to 3 years. The number of grants awarded will depend on the quality of the applications received and the availability of Federal funds to support the grant. These grants are not intended to fund food, medical devices, or drug inspections. Only one award will be made per State.

State Health Fraud Task Force grants will be awarded for up to 3 years based on availability of funds and satisfactory performance. The budgets for all years of requested support must be fully justified in the original application.

Support for this program will be in the form of a grant.

1. Award Amount

It is anticipated that each year approximately $300,000 will be available for this program. FDA anticipates making approximately 20 awards, not to exceed $15,000, in direct costs only per award per year.

2. Length of Support

It is anticipated that FDA will fund these grants at a level requested but not exceeding $15,000 total direct costs only for the first year. An additional 2 years of support up to approximately $15,000 total direct costs only each year will be available, depending upon the following factors: (1) Performance during the preceding year, (2) compliance with regulatory requirements of the award, and (3) availability of Federal funds.

3. Funding Plan

The number of grants funded will depend on the quality of the applications received, their relevance to FDA's mission, priorities, and the availability of funds.

III. Eligibility Information

Applicants are limited to States that have an existing AIDS Health Fraud Task Force or States that are in the process of developing a Health Fraud Task Force.

1. Eligible Applicants

This grant program is only available to one State Health Fraud Task Force per State.

2. Cost Sharing or Matching

None.

3. Other

An application will be considered nonresponsive if any of the following circumstances are met: (1) If it is received after the specified receipt date; (2) if the total dollar amount requested from FDA exceeds $15,000 per year; (3) if all required original signatures are not on the face, assurance, or certification

pages of the application; (4) if there is no original signature copy; (5) if it is illegible; (6) if the material presented is insufficient to permit an adequate review; or (7) if the application demonstrates an inadequate understanding of the intent of the Request For Application (RFA).

A fiscal agent, who will be responsible for the administrative responsibilities for grant funds to conduct their activities, must be identified on the application. A program director, also known as the State Health Fraud Task Force Chair, must be identified as being responsible for submission of the application, and a complete listing of all State Health Fraud Task Force members and their credentials must be included in the application.

Responsiveness is defined as submission of a complete application with original signatures on or before the required submission date as listed previously in this document. If an application is found to be nonresponsive, it will be returned to the applicant without further consideration.

IV. Application and Submission

1. Address to Request Application

FDA is accepting new applications for this program electronically via Grants.gov. Applicants are strongly encouraged to apply electronically by visiting the Web site *http://www.grants.gov* and following instructions under "APPLY." The applicant must register in the Central Contractor Registration (CCR) database in order to be able to submit the application electronically. Information about CCR is available at *http://www.grants.gov/CCRRegister.* The applicant must register with the Credential Provider for Grants.gov. Information about this requirement is available at *http://www.grants.gov/CredentialProvider.* (FDA has verified the Web site address, but FDA is not

responsible for subsequent changes to the Web site after the document publishes in the **Federal Register**).

If applicants experience technical difficulty with online submissions, applicants should contact either Djuana Gibson, Division of Contracts and Grants Management (HFA–500), Food and Drug Administration, 5600 Fishers Lane, rm. 2141, Rockville, MD 20857, 301–827–7177, e-mail: *dgibson@oc.fda.gov*, or the Grants.gov Contact Center at 1–800–518–4726. An application not received in time for orderly processing will be returned to the applicant without consideration.

2. Content and Form of Application

Applicants are strongly encouraged to contact FDA to resolve any questions regarding criteria prior to the submission of their applications. All questions of a technical or programmatic nature must be directed to the Office of Regulatory Affairs (ORA) program staff (see section VII of this document) and all questions of an administrative or financial nature must be directed to the grants management staff (see section IV.1 of this document).

No supplemental material or addenda will be accepted after the receipt date.

A properly formatted sample application for grants can be accessed on the Internet at *http://www.fda.gov/ora/fed_state/Innovative_Grants.html.*

The face page of the application should indicate "Response to RFA–FDA–ORA–04–2."

The Division of Federal-State Relations will provide meeting guidelines and organization documents as requested.

3. Submission Dates and Times

The application receipt date for fiscal year 2005 is [*insert date 30 days after date of publication in the* **Federal Register**] for new applications. Each subsequent year that this program is in effect the receipt date will be April 30.

Applications will be accepted from 8 a.m. to 4:30 p.m., Monday through Friday, until the established receipt date.

4. Intergovernment Review

The regulations issued under Executive Order 12372, Intergovernmental Review of Department of Health and Human Services Programs and Activities (45 CFR part 100), apply to this program. Executive Order 12372 sets up a system for State and local government review of applications for Federal financial assistance. Applicants (other than federally recognized Indian tribal governments) should contact the State's Single Point of Contact (SPOC) as early as possible to alert the SPOC to the prospective application(s) and to receive any necessary instructions on the State's review process. A current listing of SPOCs is included in the application kit or at *http://www.whitehouse.gov/omb/grants/spoc.html*. (FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after the document publishes in the **Federal Register**). The SPOC should send any State review process recommendations to FDA's administrative contact (see section IV.1 of this document). The due date for the State process recommendations is no later than 60 days after the deadline date for the receipt of applications. FDA does not guarantee to accommodate or explain SPOC comments that are received after the 60-day cutoff.

5. Funding Restrictions

Examples of direct costs may include the following items: (1) Conferences/ workshops sponsored by the task force, (2) development of public service announcements/campaigns, (3) health fraud brochures, and (4) travel expenses for face-to-face State Health Fraud Task Force meetings. Grant funds may be used to cover the cost of the program director, or task force chair, to attend one non-FDA sponsored health fraud related meeting and one FDA-sponsored National Health Fraud Task Force Steering Committee meeting per year. Grant funds may not be used to purchase meals in conjunction with any activities sponsored by the State Health Fraud Task Force or for any Federal employee to travel to any task force meeting or to participate in any task force activity. FDA region/district representatives may be invited to be liaisons or advisors of the State Health Fraud Task Force but each task force should develop its own guidelines for work, consensus decisionmaking, size, and format.

6. Other Submission Requirements

Do not send applications to the Center for Scientific Research, National Institutes of Health (NIH). Any application sent to NIH that is then forwarded to FDA and not received in time for orderly processing will be deemed unresponsive and returned to the applicant. FDA is able to receive applications via the Internet.

Since October 1, 2003, applicants are required to have a DUNS number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a 9-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, call 1–866–705–5711. Be certain that you

identify yourself as a Federal grant applicant when you contact Dun and Bradstreet.

V. Application Review Information

1. Criteria

Applications will be given an overall score and judged based on all of the following criteria equally: (1) The content/subject matter and how current and appropriate it is for FDA's mission; (2) the educational outreach plan and how thorough, reasonable, and appropriate it is for accomplishing the mission of the program; (3) the experience, training, and competence of the program director and task force members as described in the application; (4) the reasonableness of the proposed budget given the plan for achieving the objective of the mission of the State Health Fraud Task Force Program; (5) a plan for self-sustaining the task force program in the event that Federal funding were to become unavailable in the future; (6) a brief history of the existing State Health Fraud Task Force and its accomplishments, not to exceed two typewritten pages; (7) a description of the structure of the existing State Health Fraud Task Force including such items as nonprofit organizational status, membership guidelines, or other relevant information to demonstrate the task force as a recognizable structured entity.

2. Review and Selection Process

This program is primarily intended for previously established Health Fraud Task Forces. However, consideration will be given to newly formed task forces that meet the requirements of this RFA.

All applications submitted in response to this RFA will first be reviewed by grants management and program staffs for responsiveness.

Responsive applications will be reviewed and evaluated for scientific and technical merit by an ad hoc panel of experts in the subject field of the specific application. Applications will be considered for funding on the basis of their overall technical merit as determined through the review process. Other award criteria will include availability of funds and overall program balance. Funding decisions will be made by the Commissioner of Food and Drugs or his designee.

VI. Award Administration Information

1. Award Notice

FDA's Grants Management Office will notify applicants who have been selected for an award. Awards will either be issued on a Notice of Grant Award (Public Health Service (PHS) 5152) signed by the FDA Chief Grants Management Officer and be sent to the applicant by mail or transmitted electronically.

2. Administrative and National Policy Requirements

These grants will be subject to all policies and requirements that govern the project grant programs of PHS, including the provisions of 42 CFR part 52, 45 CFR parts 74 and 92, and the PHS Grants Policy Statement.

FDA urges applicants to submit work plans that address specific objectives of "Healthy People 2010." Applicants may obtain a paper copy of the "Healthy People 2010" objectives, vols. I and II, for $70 ($87.50 foreign), S/N 017–000–00550–9, by writing to the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 371954, Pittsburgh, PA 15250–7954. Telephone orders can be placed to 202–512–2250. The document is also available in CD–ROM format, S/N 017–001–00549–5, for $19 ($23.50 foreign), as well as on the Internet at *http://www.health.gov/healthypeople/* under "Publications."

(FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after the document publishes in the **Federal Register**).

3. Reporting

Semiannual progress reports as well as a final program progress report are required. The grantee must submit a progress report and two copies to FDA's grants management officer in the middle of each budget period and also within 90 days after the end of each budget period. The final progress report, due 90 days after the end of the project period, must provide full written documentation of the project, copies of any results (as described in the grant application), and an analysis and evaluation of the results of the project.

An annual financial status report (FSR) is due 90 days after the end of each budget period. The final FSR is due 90 days after the end of the project period.

Program monitoring of recipients will be conducted on an ongoing basis and written reports will be reviewed and evaluated at least semiannually by the project officer. Project monitoring may also be in the form of telephone conversations between the project officer/grants management specialist and the principal investigator and/or a site visit with appropriate officials of the recipient organization. The results of these monitoring activities will be recorded in the official file and may be available to the recipient upon request consistent with applicable disclosure statutes and with FDA disclosure regulations.

VII. Agency Contacts

Regarding the administrative and financial management aspects of this notice: Djuana Gibson (see section IV.1 of this document).

Regarding the programmatic aspects of this notice: Stephen Toigo,

Division of Federal-State Relations (HFC–150), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, rm. 12–07, Rockville, MD 20857, 301–827–6906, or access the Internet at *http://www.fda.gov/ora/fed_state/default.htm.* For general ORA program information contact your Public Affairs Specialists at *http://www.fda.gov/ora/fed_state/DFSR_Activities/.*

VIII. Other Information

Data included in the application, if restricted with the legend specified in this section of the document, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on PHS Form 5161–1 were approved and issued under Office of Management and Budget Circular A–102.

Unless disclosure is required under FOIA as amended (5 U.S.C. 552), as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of an

application that have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted and/or proprietary information, shall not be used or disclosed except for evaluation purposes.

Dated: 7/6/05
July 6, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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